

The rejection acknowledges that Hoffman does not disclose a TTS wherein the matrix comprises a support material that consists of paper. Office Action at 3. In order to correct the deficiency, the rejection relies upon Nichols alleging that this patent discloses a TTS wherein the matrix material is “made of absorbent paper.” *Id.* The rejection then concludes that one of ordinary skill in the art:

would have been motivated to substitute the matrix of Nichols into the structure of Hoffman in order to improve ... the transmission of the active agent, specifically estradiol.

Office Action at 4. Applicants respectfully disagree since Nichols discloses using paper as a carrier material and not as a support material, as called for in the present claims. As Nichols is silent with respect to using paper as a support material in a TTS, it cannot correct the deficiencies found in Hoffman and the rejection does not establish a *prima facie* case of obviousness.

This present invention provides for a TTS in which the active agent depot or the matrix comprises paper as a support material. As discussed on pages 1 to 3, the prior art does not teach using paper for this purpose and the prior materials used as support material used a TTS are fundamentally different from paper (see especially page 2, line 19 *et seq.*). Moreover, the use of paper as a support material for these components has distinct advantages over the prior material, such as fabrics. Examples 1 and 2 demonstrate some of these advantages.

Hoffman provides for a conventional TTS. As discussed on page 2, line 25 *et seq.*, the depot and the matrix components do not contain paper. The support materials disclosed in Hoffman, which distribute the active substance within the fabric, are planar fabrics, such as a nonwoven fabric such as cotton (see col. 3, lines 10 to 19; col. 7, line 18 to 20). Thus, not only is Hoffman “silent” with respect to the inclusion of paper for these components, the patent teaches

away from the use of paper since paper has properties which are different from fabrics (see page 2, third paragraph of the specification).

Nichols does not correct this deficiency. The compositions provided for in Nichols comprise a solution of a medicament in benzyl alcohol. This solution may be in the form of thickened solution, which is applied or coated directly on the skin (col. 2, lines 33-39), a semi-solid adhesive layer, which contains the benzyl alcohol solution of the medicament (col. 2, lines 41-46), or an absorbent pad of a fibrous material or a porous benzyl-alcohol-insoluble polymeric matrix, which contains the porous benzyl alcohol solution of the medicament (col. 2, lines 50-54), the latter being preferred. The composition further comprises a bandage or covering, which fixes the composition to the skin confining the medicament solution (col. 2, lines 47-50) and provides a means for keeping the carrier in contact with the skin. Materials for the absorbent pad or fibrous material are said to be absorbent paper, fibrous batts and various porous or microporous polymeric gels (col. 3, lines 2-5).

Thus, Nichols teaches a composition for the dermal administration of a medicament. The composition comprises a backing material that is impermeable to active agents, an adhesive component, and a carrier, which can be made of absorbent paper containing a benzyl alcohol solution of a medicament, such as estradiol. However, Nichols does not disclose a TTS wherein the active agent depot, matrix or both comprise a support material, wherein the support material consists of paper.

Therefore, Nichols merely discloses various materials that are suitable carriers which will absorb a benzyl alcohol solution of a medicament. However, Nichols is absolutely “silent” with regard to paper as a support material. Nichols does not provide any guidance to the practitioner on how to make the active substance depot insensitive to pressure and tension while

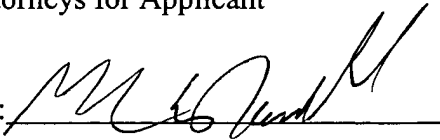
increasing the uniformity and make the production of TTS better. Hence, Nichols with does not provide any motivation to include paper as a support material in a TTS.

Thus, in view of the foregoing it is urged that the rejection does not establish a *prima facie* case of obviousness and the withdrawal of this rejection is requested.

Favorable action is earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG
Attorneys for Applicant

By: 

Mark W. Russell
Reg. No. 37,514
Tel.: (212) 588-0800
Fax: (212) 588-0500